UK National Screening Committee (UK NSC)

Screening for Gestational Diabetes

Date: 25 June 2021

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Aim

To ask the UK National Screening Committee (UK NSC) to make a recommendation, based on the evidence presented in this document, whether or not screening for gestational diabetes mellitus (GDM) meets the UK NSC criteria for a systematic population screening programme.

Current Recommendation

Screening for GDM in pregnant women is currently not recommended in the UK. The initial UK NSC recommendation not to introduce a GDM screening programme was based on a 2002 Health Technology Assessment (HTA) report which concluded that screening for GDM did not meet sufficient UK NSC criteria. A precise definition of GDM was lacking and adverse outcomes of increased glucose levels were reported mostly as macrosomia, the thresholds for which were considered somewhat arbitrary and not distinguishing between larger babies and those with abnormal growth, where treatment may be beneficial. No standardised test to screen for GDM was available and there was a concern that some women with low levels of glucose intolerance

and who are not at risk of adverse outcomes may suffer anxiety and inconvenience due to receiving the diagnosis.

This was followed by another HTA, in 2010, which incorporated the findings of the Hyperglycaemia and Adverse Pregnancy Outcome (HAPO) and Australian Carbohydrate Intolerance Study in Pregnant Women (ACHOIS) studies, and despite finding an increased knowledge base around the condition, there was still insufficient evidence to determine blood glucose levels at which interventions may provide benefit. Currently, the risk-factor based testing is recommended by NICE, but it is unclear whether women without the NICE -specified risk factors could be at risk of adverse outcomes if their blood glucose values are elevated but not yet reaching the 7.8 mmol/L threshold specified by NICE.

Evidence Summary

The 2021 evidence summary was undertaken by Costello Medical and in accordance to the UK NSC triennial evidence review process.

The scope of the 2021 evidence summary was to look at 3 questions on the criteria addressing the natural history, the screening strategy and the effectiveness of intervention in the screen detected population.

This rapid review aims to identify evidence published since the last HTA report searches which were conducted in 2009, in answer to the following questions:

- Q1: What are the risks of short and long-term adverse outcomes associated with incremental increases in maternal blood glucose level in the newborn?
- Q2: What are the most effective screening tests or strategies to identify women at risk of hyperglycaemia in pregnancy or GDM?
- Q3: What is the most effective intervention for lowering glucose levels in screen-detected pregnant women with GDM and preventing adverse perinatal outcomes?

Searches for Q1 and Q2 were based on a large systematic literature review Farrar 2016, whose searches were conducted in October 2014 and were updated as part of this review.

For Q3, the 3 Systematic literature reviews (SLRs) that formed the evidence base only included RCT evidence. As such, only the search results identified through the RCT search filter were date limited to 2016. Non-RCTs and observational studies were date limited to 2009.

The conclusion of the 2021 evidence summary is that population screening for gestational diabetes should not be recommended. However, NICE guidelines should still be adhered to for women at high risk

Question 1; the aim of this question was to identify associations between incremental increases in glucose levels that are elevated from normal in a low risk population (for example; those not considered to have GDM according to NICE criteria or those treated for GDM) and the risks of adverse pregnancy and neonatal outcomes. This would allow the characterisation of a "low risk" population that may benefit from screening for GDM who are not currently included in the NICE recommendation.

For this question, moderate-to-high quality evidence for a wide number of pregnancy and neonatal outcomes was identified. The evidence was judged to be broadly applicable to the UK clinical setting. However, applicability to the review question was limited, as in most studies, the population of mild hyperglycaemia overlapped with women considered to be at high risk of GDM as covered by the NICE guideline. Only 2 studies limited inclusion to low risk women with only mild hyperglycaemia who would not be considered at risk by the NICE guideline.

The review identified clear associations from a large volume of evidence between elevated glucose and increased risk of several outcomes: C-section, induction of labour, macrosomia and large for gestational age (LGA). The latter 2 outcomes were also significantly increased in women who would not currently be identified as at risk by the NICE guideline. Nevertheless, a clear glucose threshold for increased risk could not be identified for any outcome, mostly due to the limited evidence on single thresholds. This is supported by the finding from previously published work, that there is a continuum of risk across increasing glucose levels and no clear cut-off point. On this basis, **Criterion 1 was not met**.

Question 2; although, the review found a large and reasonable quality of the evidence, none of the studies found a screening strategy that achieved test accuracies where both specificity and sensitivity were high enough to consider the test reliable and able to replace the current test (2-hour 75 g oral glucose tolerance test (OGTT)), which involves glucose loading and therefore poses some risk of harm to women who are already suspected to be at risk of glucose intolerance. Using any of those strategies and only applying OGTT in screen-positive women would likely miss a considerable proportion of GDM (at a high threshold) or result in most women having to undergo OGTT anyway (at a lower threshold). Therefore, the best currently available test is the diagnostic OGTT test. This has drawbacks of uncertainty around its accuracy (vs a different reference standard or clinical diagnosis), as well as the risk of harm of glucose loading, with unknown consequences should it be used in all pregnant women. Given the uncertainty around the accuracy and acceptability of the OGTT test (if used for screening) and lack of a better test: **Criterion 4 was not met**.

Question 3; there is a moderate-to-high quality evidence consisting of a total of 34 RCTs reported across 4 SLRs and 7 primary publications in women with GDM treated with insulin, glibenclamide/glyburide, metformin or lifestyle interventions, such as diet or exercise. However, only 1 study included a confirmed screen detected GDM population and few studies compared interventions with placebo or usual care. In clinically diagnosed GDM, none of the interventions could be shown to be consistently better than the other. It is therefore likely that they are similarly effective. While their benefit over no treatment is not certain, the benefit of interventions examined in this review against no treatment has been demonstrated previously, most notably by the ACHOIS study.

Due to the lack of evidence in women with screen detected GDM it is difficult to demonstrated that the interventions that are beneficial in population that are clinically diagnosed with GDM are of benefit when applied to women who are screen-detected with the condition: **Criterion 9 was not met**.

In summary,

Gestational diabetes mellitus and hyperglycaemia are important health problems and with a moderately safe treatment available in women where the condition is diagnosed following a risk-factor based testing or presentation with symptoms. However, it is unclear whether benefits would outweigh the harms if universal screening for GDM were to be introduced. This is because of uncertainties around the thresholds at which women should be considered at risk; the lack of a safe and practical test or lack of data supporting the use of OGTT as a screening test; and lack of data supporting benefits from currently available interventions in screen-detected women.

Refer to table A below for criteria.

Consultation

A three-month consultation was hosted on the UK NSC website. Direct emails were sent to 16 stakeholders. (Appendix A)

Comments were received from the following 3 stakeholders (see appendix B for comments):

- The Royal College of Midwives;
- The Association of British Clinical Diabetologists;
- The Royal College of Physicians

None of the consultation responses disagree with the conclusion of the review; however, they all noted that the review should have concentrated on ‘high risk’

groups not on screening in the general population. This is because there is a general concern that women who are most at risk of developing GDM (women of ethnic minority origin, those with a family history of diabetes, and those who are obese) are not equality look after across the country because there is there is wide variability in the provision of testing for GDM across the UK.

Recommendation

The Committee is asked to approve the following recommendation:

A systematic population screening for GDM is not recommended in the UK. However, NICE guidelines should still be adhered to for women at high risk.

UK National Screening Committee

Section 1 - Criteria for appraising the viability, effectiveness and appropriateness of a screening programme

This section looks at whether certain UK NSC criteria have been met when reviewing a given screening programme. Only the criteria evaluated by the current review have been included below.

The Condition

Criterion 1: The condition should be an important health problem as judged by its frequency and/or severity. The epidemiology, incidence, prevalence and natural history of the condition should be understood, including development from latent to declared disease and/or there should be robust evidence about the association between the risk or disease marker and serious or treatable disease.

- **Criterion 1 has not been met**

Criterion 2: All the cost-effective primary prevention interventions should have been implemented as far as practicable.

The Test

Criterion 4: There should be a simple, safe, precise and validated screening test.

- **Criterion 4 has not been met**

The Intervention

Criterion 9: There should be an effective intervention for patients identified through screening, with evidence that intervention at a pre-symptomatic phase leads to better outcomes for the screened individual compared with usual care. Evidence relating to wider benefits of screening, for example those relating to family members, should be taken into account where available. However, where there is no prospect of benefit for the individual screened then the screening programme shouldn't be further considered.

- **Criterion 9 has not been met**

UK National Screening Committee

Appendix A: List of Organisations Contacted

1. Association for Improvements in the Maternity Services
2. British Association of Perinatal Medicine
3. British Society for Immunology
4. Diabetes UK
5. Faculty of Public Health
6. Institute of Child Health
7. National Childbirth Trust
8. PHE ANNB Screening Programmes
9. Royal College of General Practitioners
10. Royal College of Midwives
11. Royal College of Obstetricians and Gynaecologists
12. Royal College of Paediatrics and Child Health
13. Royal College of Physicians
14. Royal College of Physicians and Surgeons of Glasgow
15. Royal College of Physicians of Edinburgh
16. Scottish Diabetes Group Diabetes and Pregnancy subgroup

UK National Screening Committee

Appendix B: Consultation Responses

Note: Personally identifiable information has been redacted from certain comments, where individuals have chosen not to have personal details made public

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1)

Name:	Mervi Jokinen	**Email address:**	XXXX XXXX
Organisation (if appropriate):	Royal College of Midwives		
Role:	**Professional Advisor**		

Do you consent to your name being published on the UK NSC website alongside your response?

Yes x **No**

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required***.**
Executive summary P10	**Based on the evidence identified in this review, population screening for GDM is still not recommended. However, NICE guidelines should still be adhered to for women at high risk.**	RCM agrees with the current and reviewed recommendation of not introducing population screening for Gestational Diabetes. NICE guidelines are developed with multi-professional consensus and information for women is provided accordingly in local maternity services. The current review of evidence on consultation does not assure RCM that new technology or interventions are identified to improve screening, diagnosis or treatment of gestational diabetes. Gestational Diabetes Mellitus (GDM) remains a 'high risk' condition in pregnancy and the current data of increased BMI in pregnant population, in deprived areas/regions, is of concern. This will increase the need for and burden of diagnostic testing in pregnancy. The pre-conceptual education

		early on linking obesity and other risk factors with GDM and advising women with GDM post pregnancy may be more cost-beneficial use of funds. PHE (2019) Health of women before and during pregnancy: health behaviours, risk factors and inequalities An updated analysis of the maternity services dataset antenatal booking data

2)

Name:	Susannah Rowles	**Email address:**	XXXX XXXX
Organisation (if appropriate):	Association of British Clinical Diabetologists (ABCD)		
Role:	**Submitted on behalf of ABCD by Honorary Secretary S Rowles with in put from Prof Eleanor Scott**		
Do you consent to your name being published on the UK NSC website alongside your response? **Yes**			

Section and / or page number	**Text or issue to which comments relate**	**Comment** *Please use a new row for each comment and add extra rows as required***.**
General	**General**	We're very pleased that Gestational Diabetes has been the focus of this screening review as it is a significant, common condition that affects many, otherwise seemingly healthy, women of childbearing age in the UK. It is of considerable relevance to ABCD and the wider NHS. We are therefore somewhat disappointed by this National Screening Programme review. We consider that the content of this review falls way short of the expectations from the title and in doing so perpetuates the inequalities in care that exist. It is unclear why the review chooses to focus on

		whether or not to offer screening to low risk women, instead of addressing how to systematically tackle the deficiencies in screening, detecting and managing high risk women for GDM. The adverse short- and long-term health outcomes of gestational diabetes (GDM) for the mother and her offspring are now well established (Saravanan P et al *Lancet Diabetes Endocrinol. 2020 Sep;8(9):793-800).* Furthermore maternal & child health and wellbeing have a causal effect on transgenerational population health, and policies focusing on the health of women and children are expected to produce a fairer, stronger and more resilient society (Modi N et al. BMJ 2021;373:n899). The evidence for screening pregnant women for GDM is therefore clear. This review appears to conclude that screening 'high risk' women for GDM is evidence-based as clearly documented in NICE (NG3) but that as the NICE guidance exists there appears no need to offer this as part of a National Screening Programme. This assumes that NICE guidance is adhered to across the UK, but in reality there is wide variability in the provision of screening for GDM across the UK, and in the absence of it being adopted by the National Screening Programme it seems likely to us that these inequalities will be perpetuated. This is concerning as the women who are most at risk of developing GDM are women of ethnic minority origin, those with a family history of diabetes, and those who are obese. Not only do these risk factors affect over half of all pregnant women, but they are also predominantly seen in women who are socioeconomically the most deprived. Hence, we feel that an opportunity to improve the inequalities in maternal and child health in the UK has been missed by this screening review. The next time this subject is revisited for consideration of screening – we respectfully suggest that the focus is on whether women at 'high risk' for GDM should be included in a National Screening Programme, as the answer would then be yes and progress could be made in this extremely important area.

UK National Screening Committee

3)Dear all

The RCP is grateful for the opportunity to respond to the above consultation.

We would like to endorse the response submitted by the Association of British Clinical Diabetologists (ABCD)
I would be grateful if you could confirm receipt.

Best wishes

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